

K 122491

510(k)-SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with 21 CFR 807.92, the following summary of the information is provided.

SEP 13 2012

1. **Submitter's Name:**
Toshiba America Medical Systems, Inc.
2. **Submitter's Address:**
2441 Michelle Drive
Tustin, CA 92781-2068
3. **Establishment Registration Number:**
2020563
4. **Contact Person:**
Charlemagne Chua
Manager Regulatory Affairs
(714) 730-5000
5. **Date Prepared:**
July 2, 2012

6. **Manufacturer:**
Panasonic Healthcare Co., Ltd

Manufacturer Address 1: 600 Saedo-cho, Tsuzuki-ku
Yokohama, Japan 224-8539

Establishment Registration Number: 8030237

Manufacturer Address 2: 247 Fukutake-ko
Saijo, Japan 793-8510

Establishment Registration Number: 3007582674

7. **Distributor:**
Toshiba Medical Systems Corporation
8. **Distributor Address:**
1385 Shimoishigami
Otawara-Shi, Tochigi-Ken, Japan 324-8550
9. **Device Proprietary Name:**
VIAMO MODEL SSA-640A V4.0
10. **Common Name:**
Diagnostic Ultrasound System
11. **Classification:**
Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
[Fed.Reg.No.:892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO
[Fed.Reg.No.:892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX
[Fed. Reg. No.: 892.1570]

12. Predicate Device:

Viamo SSA-640A v2.0 Ultrasound System, Toshiba America Medical Systems, Inc., K100067.

13. Device Description:

Viamo V4.0 is a Track 3 ultrasound system. It is a full-digital system that utilizes a wide range of probes (flat linear array, convex array and sector array) with a frequency range of approximately 2.5 MHz to 12 MHz. The slim pole-cart allows the system to be easily moved in the medical facility to perform examinations. The main unit, which can be detached from the cart by one-touch operation, is powered by an internal battery.

14. Indications for Use:

The VIAMO Diagnostic Ultrasound System is indicated for the visualization of structures, characteristics and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, trans-vaginal, neonatal cephalic, adult cephalic, cardiac, peripheral vascular and musculo-skeletal (both conventional and superficial).

15. Technological characteristics:

The Viamo V4.0 employs the same fundamental scientific technology as its predicate device.

16. New Feature:

Addition of two transducers:

The PVT-712BT for trans-vaginal and the PST-50BT for abdominal, pediatric, neonatal cephalic, adult cephalic, cardiac adult, cardiac pediatric are added to the Viamo.

Addition of Vascularity Index:

The “Vascularity Index” provides the area of the power mode where blood is flowing.

Addition of a new display format for dual images:

This is a new display format for dual image mode.

17. Determination of Substantial Equivalence:

The addition of the two transducers, PVT-712BT and PST-50BT, do not change the cleared intended use of the Viamo V2.0, K100067. And the addition of the Vascularity Index does not change the effectiveness and safety of the device.

The materials, hardware, method of operation, base software and manufacturing process remain unchanged from the predicate device. The Viamo SSA-640A V4.0

incorporates two new features including a display of the Vascularity Index and a new image display format for dual images. Additionally, two transducers were added for use with VIAMO MODEL SSA-640A V4.0. This device is substantially equivalent to the Viamo SSA-640A V2.0, K100067.

18. Safety:

This device is designed and manufactured under the Quality System Regulations as outlined under 21 CFR§820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC 60601-1(2005), IEC 60601-1-2(2007), IEC 60601-2-37(2007) and the AIUM-NEMA UD3 Output Display Standard.

19. Summary of Testing:

a. Bench Test

- The B mode accuracy and Doppler mode velocity accuracy tests were conducted confirm the effectiveness for the added two transducers. And electrical, thermal tests and acoustic power test were conducted to confirm the safety.
- The accuracy test of the Vascularity Index was conducted to confirm the effectiveness.

b. Clinical Test

Viamo V4.0 did not require clinical studies to support substantial equivalence.

20. Conclusion:

The new features being added to the subject device do not change the indication for use or the intended use of the device. Based upon the safety and effectiveness data/information provided, the clinical performance of VIAMO MODEL SSA-640A V4.0 is deemed to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 13 2012

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K122491

Trade/Device Name: VIAMO MODEL SSA-640A V4.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 30, 2012
Received: August 31, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the VIAMO MODEL SSA-640A V4.0, as described in your premarket notification:

Transducer Model Number

PST-25ST
PVT-375ST
PLT-704ST
PLT-805AT
PVT-382BT

PLT-1204BT
PVT-674BT
PVT-661VT
PVT-745BT
PVT-705BTH

PLT-704ST
PST-50BT
PVT-712BT

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Gary Levine at (301) 796-6934.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K122491/51

Device Name: VIAMO MODEL SSA-640A V4.0

Indications for Use:

The **VIAMO** Diagnostic Ultrasound System is indicated for the visualization of structures, characteristics and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, trans-vaginal, neonatal cephalic, adult cephalic, cardiac, peripheral vascular and musculo-skeletal (both conventional and superficial).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)

Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122491

System: Viamo Model SSA-640A v4.0 Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			3,4
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			3,4
Small Organ (Note 1)	P	P	P		P	2	P	P	P			3,4
Neonatal Cephalic	P	P	P		P	2	P	P	P			3,4
Adult Cephalic	P	P	P		P	2	P	P	P			3,4
Trans-rectal												
Trans-vaginal	P	P	P		P	2	P	P	P			3,4
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			3,4
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			3,4
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P		P	2	P	P	P			3,4
Cardiac Pediatric	P	P	P		P	2	P	P	P			3,4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K100067


Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K122491

System: Viamo Model SSA-640A v4.0

Transducer: PST-25ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Advanced Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			3,4
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P		P	2	P	P	P			3,4
Adult Cephalic	P	P	P		P	2	P	P	P			3,4
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P		P	2	P	P	P			3,4
Cardiac Pediatric	P	P	P		P	2	P	P	P			3,4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K100067

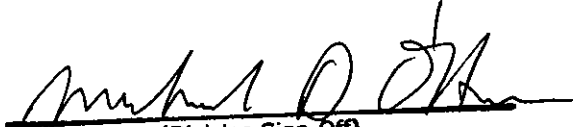
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K102491 Q1VD

System: Viamo Model SSA-640A v4.0

Transducer: PVT-375ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			3,4
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			3,4
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K100067

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k 6122491

System: Viamo Model SSA-640A v4.0
 Transducer: PLT-704ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			3,4
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			3,4
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			3,4
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

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 Previous 510(k) of the transducer: K100067

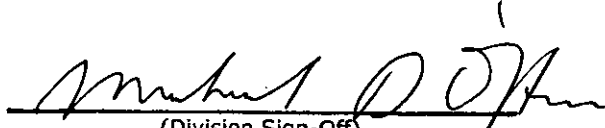
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 510k K122491

System: Viamo Model SSA-640A v4.0

Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			3,4
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			3,4
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			3,4
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

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Previous 510(k) of the transducer: K100067

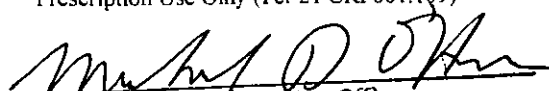
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k K122491

System: Viamo Model SSA-640A v4.0

Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			3,4
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			3,4
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducer: K100067

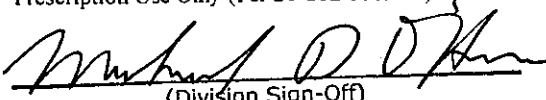
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K100067

System: Viarno Model SSA-640A v4.0
 Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			3,4
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

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 Previous 510(k) of the transducer: K100067


Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 510k 6122491

System: Viamo Model SSA-640A v4.0

Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			3,4
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			3,4
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k K122491

System: Viamo Model SSA-640A v4.0

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal	P	P	P		P	2	P	P	P			3,4
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducer: K100067

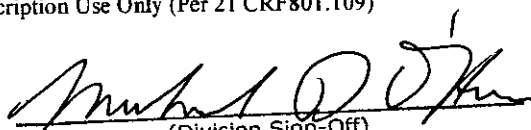
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k 6122491

System: Viamo Model SSA-640A v4.0
 Transducer: PVT-745BTB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K100067

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)

Division of Radiological Devices

510k K122491

System: Viamo Model SSA-640A v4.0

Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K100067

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k

K122491

System: Viamo Model SSA-640A v4.0

Transducer: PLT-704ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			3,4
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			3,4
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K100067

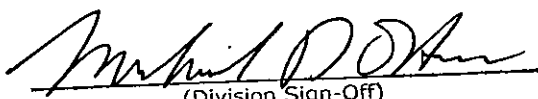
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Radiological Devices
510k K122491

System: Viamed Model SSA-640A v4.0

Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Advanced Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			3,4
Small Organ (Note 1)												
Neonatal Cephalic	N	N	N		N	2	N	N	N			3,4
Adult Cephalic	N	N	N		N	2	N	N	N			3,4
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N		N	2	N	N	N			3,4
Cardiac Pediatric	N	N	N		N	2	N	N	N			3,4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: N/A. This is new

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Radiological Devices

510k K122491

System: Viamo Model SSA-640A v4.0
 Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Advanced Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			3,4
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			3,4
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N		N	2	N	N	N			3,4
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: N/A. This is new

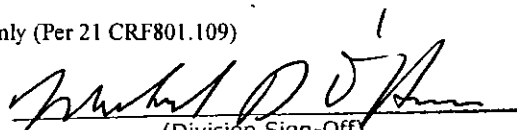
Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 ApliPure

Note 4 Vascularity Index: added under this submission

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 510k K122491